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REMARKS

This Amendment is responsive to the Office Action dated January 17, 2007. Applicant has amended claims 1, 12, 13, 15-17, 22, 30 and 33, cancelled claim 32, and added a new claim 34. Claims 1-24 and 26-31, 33 and 34 are pending. In view of the above amendments and the following remarks, Applicant respectfully requests reconsideration of the rejections set forth in the Office Action.

Claim Objections

The Office Action objected to claims 12, 15 and 32 as "containing inadvertent typographical errors." Although Applicant does not agree that each of claims 12, 15 and 32 included typographical or grammatical errors as previously presented, each of these claims has been amended in an attempt to alleviate the concerns underlying the objections. Claims 12 and 15 have been amended as suggested in the Office Action. Claim 32 has not been amended as suggested in the Office Action, but has been otherwise amended to provide greater grammatical clarity. Applicant respectfully requests that the claim objections be withdrawn in view of the amendments to claims 12, 15 and 32.

Claim Rejections Under 35 U.S.C. § 112

The Office Action rejected claims 1-22, 28-29 and 32-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 1 and 15-17 for purposes of clarification. Applicant submits that claims, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102/103

The Office Action rejected claims 1-3, 6, 10-11, 13-14, 17-18 and 32-33 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,638,832 to Singer et al. (herein referred to as "Singer"). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended

claims. Singer fails to disclose each and every feature of the claimed invention, and provides no teaching that would have suggested the desirability of modification to include such features.

Applicant has amended independent claim 1 to further recite a therapy delivery element to deliver a therapy to a brain of a patient, and control electronics to control the delivery of the therapy by the therapy delivery element, wherein the therapy delivery element and the control electronics are located within one of the modules. These limitations are substantially similar to those recited by claim 22 as previously presented, which depends from independent claim 1. This amendment to independent claim 1 is supported throughout the application as originally filed, including, for example, claim 22, and paragraphs [0039], [0045] and [0056]. Claim 22 has been amended to recite that the therapy is stimulation, i.e., claim 22 continues to require delivery of stimulation to the brain, and control circuitry to control delivery of stimulation to the brain.

Applicant notes that claim 22, as previously presented, was not rejected under sections 102 and 103. Furthermore, Singer fails to disclose or suggest a therapy delivery element to deliver a therapy to a brain of a patient, and control electronics to control the delivery of the therapy by the therapy delivery element, wherein the therapy delivery element and the control electronics are located within one of the modules, as required by amended independent claim 1, or that the therapy is stimulation, as required by claim 22. Singer is instead directed to a display device that is visible beneath the skin. There is no teaching in any of the references applied in the Office Action that would have prompted a person of ordinary skill to modify the Singer device to deliver a therapy to a brain of the patient.

Furthermore, Singer fails to disclose or suggest that a surface of an overmold is concave along at least one axis prior to manipulation of the implantable medical device such that the surface is adapted to be implanted proximate to a cranium, as recited by amended independent claim 1. Singer does not suggest that the biologically inert capsule disclosed therein, which the Office Action argues is an overmold, is concave along at least one axis prior to manipulation of the implantable medical device such that the surface is adapted to be implanted proximate to a cranium.

In contrast, Singer describes an implantable medical device that is flexible so that it conforms to the skin's surface.[1] In rejecting claim 1, the Office Action asserted that "to conform" means "to be similar in form" or "to become similar in form" and that "to be" means "already is." In other words, the Office Action relies on a linguistics exercise for the apparent argument that the phrase "to conform" in Singer means "already was conforming prior to implantation."

Singer, however, does not state, or even seem to consider, that the medical device has any concavity prior to manipulation. Singer teaches that the medical device may be implanted in many locations within the body[2], which suggests that the device is able to take on any of a variety of shapes upon implantation including concave, convex, or flat shapes, and also combinations of these shapes. The device 10 shown in Figure 1, the programming device 32 in Figure 3 and the control module 12 in Figure 4 are not specified as concave prior to manipulation; they are simply conforming to the skin's surface after implantation.

Furthermore, having a well-defined curvature, namely concavity, prior to manipulation of the medical device would hinder the applicability of the medical device taught by Singer. For at least this reason, a person of ordinary skill in the art would not have considered it obvious to modify the Singer device to have a concavity prior manipulation.

With respect to Applicant's claim 13, Singer fails to disclose or suggest the surface of the housing of at least one of the modules is concave along at least one axis prior to manipulation of the implantable medical device. Singer teaches a medical device that is "flexible so that it conforms to the skin's surface."[3] As discussed above, this does not suggest that the device is concave prior to manipulation, only that the device is capable to conforming to the skin's surface after implantation.

With respect to Applicant's claims 14 and 17, Singer fails to disclose or suggest a medical device or part of a medical device that is concave along two axes. Figures 1 and 3-4 show medical devices that are concave along only 1 axis. Singer does not teach concavity along two axes for any medical device, thus a control module that is concave along two axes as

[1] Singer, column 2, lines 1-2.
[2] Singer, column 3, lines 10-12.
[3] Singer, column 2, lines 1-2.

required in claim 14, or a recharge module and recharge coil that are concave along two axes as required in claim 17, is not taught by Singer.

Singer fails to disclose each and every limitation set forth in claims 1-3, 6, 10-11, 13-14, 17-18 and 32-33. For at least this reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicant's claims 1-3, 6, 10-11, 13-14, 17-18 and 32-33 under 35 U.S.C. §§ 102(b) or 103(a). Withdrawal of this rejection is requested.

Claim Rejections Under 35 U.S.C. § 103

The Office Action rejected claims 7-9, 19-21 and 28-31 under 35 U.S.C. § 103(a) as being unpatentable over Singer. The Office Action also rejected claims 23-24 and 26-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,895,414 to Sanchez-Zambrano (Sanchez-Zambrano) or U.S. Patent Publication No. 2003/0017372 by Probst (Probst). Applicant respectfully traverses these rejections. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 7-9, 19-21 and 28-31

Initially, Applicant notes that claims 7-9, 19-21 and 28-29 are dependent on amended claim 1, and are also in condition for allowance over Singer for the reasons stated above with respect to amended claim 1.

Independent claim 30 has been amended to include the same limitations discussed above with respect to independent claim 1. For the reasons discussed above with respect to claim 1, Singer fails to teach or suggest the requirements of independent claim 30.

Additionally, Singer does not teach a range of radii of curvature, as recited by claim 30, as well as claims 7 and 19, or the radius of curvature recited by claims 8 and 20 In particular, Singer fails to disclose or suggest that the implantable medical device or any part of the implantable medical device, including the surface of the overmold, conforms to an arc, wherein the radius of the arc is within a range from 4.5 to 9.5 centimeters, or approximately equal to 7 centimeters. The Office Action acknowledged that Singer fails to disclose or suggest these requirements of claims 7-8. Nonetheless, relying on a holding of the Federal Circuit, the Office

Action argued that it would have been obvious for one of ordinary skill to make components of Singer conform to such arcs, because discovering optimum ranges or values of result effective variables involves only routine skill in the art.

However, this holding is not applicable to the facts at issue in the rejection of Applicant's claims based on Singer. "[A] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation."[4] The holdings on which the Office Action relies are based on optimization of a value of range disclosed in the prior art that is different from the claimed range or value.[5] Singer does not even discuss arcs or radii of curvature, much less provide a range or value for such measurements that one of ordinary skill could optimize. Accordingly, the holdings relied on in the Office Action are inapplicable to the rejection of Applicant's claims based on Singer.

Furthermore, Singer indicates that its device is flexible such that it may be implanted in a variety of locations, which would presumably have a variety of different anatomical curvatures, and there is no suggestion in Singer to implant the device described therein on the cranium. Thus, a person of ordinary skill in the art would not have considered it obvious to identify any particular range or value of radius of curvature for the Singer device, or, alternatively, would not have arrived at the range and value recited in Applicant's claims.

Applicant respectfully requests further explanation as to why the Office continues to assert that the holdings related to result effective variables are applicable in this case, or withdrawal of these rejections.

With respect to claims 28 and 29, the Office Action stated that the decision to modify the invention of Singer with metallic housings, such as stainless steel or titanium housings, would be obvious to one of ordinary skill in the art. The Office Action again relies on the mere citation of a holding. In particular, the Office Action cited *In re Lashin* for the proposition that "it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice."[6]

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[4] *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1997) (emphasis added); *see also* MPEP 2144.05.
[5] *See* MPEP 2144.05.
[6] Office Action, page 10 (emphasis added).

Applying this holding to the present facts, it is clear that the materials recited in Applicant's claims are not suitable for use in the Singer device. Singer teaches a flexible device that conforms to the skin's surface. Thus, a person of ordinary skill would not have chosen relatively rigid metallic housings, and certainly would not have chosen stainless steel or titanium housings, for use in the Singer device.

Claims 23-24 and 26-27

Sanchez-Zambrano

With respect to claim 23, Sanchez-Zambrano does not teach or suggest an implantable medical device that comprises a metallic housing. Instead, Sanchez-Zambrano teaches an acrylic housing.[7] The Office Action asserts that making the housing metallic would be an obvious design choice. However, a metallic housing is not an obvious choice in the Sanchez-Zambrano device, because a metallic housing would not provide the same advantages with respect to device weight as an acrylic. Reduced weight is a stated advantage of the Sanchez-Zambrano device.[8] Thus, this reliance on "design choice" lacks evidentiary basis, and is legally impermissible.

Furthermore, as was the case with Singer, Sanchez-Zambrano does not teach or suggest any range of radii of curvature, or even mention arc lengths or radii of curvature as result-effective variables. Moreover, even if one had been motivated to optimize the radius of curvature of the Sanchez-Zambrano device, they would have optimized it for implantation proximate to the rib cage. There is no evidence of any teaching that would have prompted a person of ordinary skill to identify an optimal range or value of radius of curvature for implantation on the cranium, or evidence suggesting that such a person would have arrived at the range and value recited in Applicant's claims. Thus, by the reasoning supplied against the rejection of claims 7-8, the rejection of claims 23 and 24 is not proper.

[7] Sanchez-Zambrano, column 2, lines 16-39.
[8] Sanchez-Zambrano, column 2, lines 25-26.

Probst

Probst does not teach or suggest an implantable medical device with an outer surface that is concave along at least two axes, as required in Applicant's claim 23. The Office Action asserts that Figures 1-4 and 6-8 depict an implantable medical device that is concave along two axes. However, the referenced figures only show concavity along one axis. For example, wall 62 depicted in FIG. 2A of Probst is only concave along one axis.

The Office Action also uses paragraphs 20-24 as support for the fact that the medical device is concave along two axes. However, these paragraphs also do not teach a device that is concave along two axes. In fact, contrary to the argument in the Office Action, these paragraphs emphasize that there is a single direction or axis of curvature. For example, paragraph [0024] of Probst states "[b]oth of the major front and back side walls 62, 64 have a curved shape of a continuous radius deflecting in a similar direction and extending from the right and left side walls 66, 68." In other words, Probst is describing a single axis of concavity for each of the surfaces defined by walls 62 and 64.

Additionally, Probst does not teach or suggest any range of radii of curvature. Similar to the above reasoning regarding Applicant claims 7-8, this does not constitute grounds for rejection of Applicant's claim 23.

This reasoning also applies to claim 24, which requires the radius of the arc be approximately equal to 7 centimeters.

Neither Probst nor Sanchez-Zambrano teach or suggest the requirements of Applicant's claims 23 and 24. Claims 26 and 27 are dependent on claim 23 and are also in condition for allowance.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 7-9, 19-21, 23-24, and 26-31 under 35 U.S.C. § 103(a). Withdrawal of these rejections is respectfully requested.

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Rejections for Obviousness-type Double Patenting:

The Office Action provisionally rejected claims 1-24 and 26-33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: (1) claims 1-21, 23-31, 33-37, 39-40, 42-53 and 55-57 of copending Application No. 10/731,869 (Amended September 13, 2006); (2) claims 1-12, 15-17 and 24-29 of copending Application No. 10/731,868 (Amended December 4, 2006); (3) claims 1-23 of copending Application No. 10/731,638 (Amended November 16, 2005); and (4) claims 1, 3-8, 10-34, 36-45, 47, 49, 51, 53-56 and 60-66 of copending Application No. 10/730,873 (Amended December 12, 2006).

Applicant notes the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied, or when the claims are otherwise allowable.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 6-14-07

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